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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,825

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Rachel Schneerson

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/559,825	<b>Applicant(s)</b> SCHNEERSON ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-22 and 34-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5, 6, 8-20, 34-44, 47-50, 54 and 57-63 is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☒ Claim(s) 21, 22, 45, 46, 51-53, 55 and 56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 11 September 2009, is acknowledged.

Claims 2, 3, 4, 8, 9, 10, 11, 12, 13, 14, 15, 57, 58, 59 and 60 have been amended.

2. Claims 1-6, 8-22 and 34-63 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claims 2-4 under 35 U.S.C. 112, second paragraph, as being indefinite for "a" polypeptide, is withdrawn in light of the amendment of the claims.

4. The rejection of claims 8-22, 50-53, 57, 58, 62 and 63 under 35 U.S.C. 112, second paragraph, as being indefinite for "synthetic homopolymer", is withdrawn in light of the amendment of the claims.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, claim 4 now recites "wherein the the synthetic". It is unclear what is meant by the use to two "the" in the sentence.

### **Double Patenting**

6. Claim 21 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 20. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

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to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 21 is the identical method of claim 20, "wherein the immune response is elicited against the poly- $\gamma$ -glutamic acid ( $\gamma$ PGA) polypeptide". The claim does not add further steps or reagents to the method of claim 20, but is merely stating an outcome of the method of claim 20.

7. Claim 22 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 20. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 22 is the identical method of claim 20, "wherein the immune response is elicited against the poly- $\gamma$ -glutamic acid ( $\gamma$ PGA) polypeptide and the carrier". The claim does not add further steps or reagents to the method of claim 20, but is merely stating an outcome of the method of claim 20.

8. Claim 45 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 44. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 45 is the identical method of claim 44 "wherein the immune response is elicited against the *Bacillus capsular* poly- $\gamma$ -glutamic acid ( $\gamma$ PGA) polypeptide". The claim does not add

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further steps or reagents to the method of claim 44, but is merely stating an outcome of the method of claim 44.

9. Claim 46 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 44. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 46 is the identical method of claim 44, "wherein the immune response is elicited against the *Bacillus* poly-γ-glutamic acid (γPGA) polypeptide and the carrier". The claim does not add further steps or reagents to the method of claim 44, but is merely stating an outcome of the method of claim 44.

10. Claim 51 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 9. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 51 recites "The conjugate of claim 9, wherein the conjugate elicits IgG anti-γDPGA antibodies in the subject". The claim is thus drawn to the same construct as is claim 9. The recitation of "wherein the conjugate elicits IgG anti-γDPGA antibodies in the subject" affords no structural or functional distinction from the conjugate of claim 9.

11. Claim 52 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 9 and claim 51. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after

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allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

Claim 52 recites "The conjugate of claim 51, wherein the conjugate also elicits IgG anti-carrier antibodies". The claim is thus drawn to the same construct as is claim 9 and in claim 51. The recitation of "wherein the conjugate elicits IgG anti-carrier antibodies" affords no structural or functional distinction from the conjugate of claim 9 or claim 51.

12. Claim 53 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 20. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 53 is the identical method of claim 20, "wherein the immune response elicits IgG anti-*B. anthracis*  $\gamma$ PGA antibodies and IgG anti-carrier antibodies in the subject". The claim does not add further steps or reagents to the method of claim 20, but is merely stating an outcome of the method of claim 20.

13. Claim 55 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 38. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 55 is the identical conjugate of claim 38, "wherein the conjugate elicits IgG anti- $\gamma$ DPGA antibodies and IgG anti-carrier antibodies in the subject". The claim is thus drawn to the same construct as is claim 55. The recitation of "wherein the conjugate elicits IgG anti-

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yDPGA antibodies and IgG anti-carrier antibodies in the subject” affords no structural or functional distinction from the conjugate of claim 38.

14. Claim 56 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 44. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 56 is the identical method of claim 44, “wherein the immune response elicits IgG anti-*B. anthracis* yPGA antibodies and IgG anti-carrier antibodies in the subject”. The claim does not add further steps or reagents to the method of claim 44, but is merely stating an outcome of the method of claim 44.

### Conclusion

15. Claim 4 is rejected. Claims 21, 22, 45, 46, 51, 52, 53, 55 and 56 are objected to.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

December 16, 2009